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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/046,030	HELLER, ZINDEL HERBERT	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *59-156* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *59-110,115,116,121,122,127,128 and 133-156* is/are rejected.

7)☒ Claim(s) *111-114, 117-120, 123-126, 129-132* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

6D

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 59-60, 65-66, 71-72, 77-78, 83-85, 90-91, 96-97, 102-103, 108-110, 115-116, 121-122, 127-128, 133-134, 139-140 and 145-146 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the determination of glucose as the first component in a blood sample in the presence of hematocrit as a second component, does not reasonably provide enablement for the determination of any and all analytes found in any biological fluid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification does not provide evidence that the concentration of any and all components (i.e. bilirubin, albumin, etc.) in any biological sample (i.e. saliva, spinal fluid, etc) is affected by the presence or concentration of a second component, and that the concentrations of all components in a biological fluid sample can be determined by the functions $i_1(t)$ and $i_2(t)$ as defined in the claims. The specification only provides evidence that glucose and hematocrit in a blood sample can be determined by these functions.

3. Claims 133-156 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On lines 10 and 14 of claim 133, the terms "performing" and "removing" are indefinite since these are method steps, and claim 133 recites an apparatus. These terms on lines 10 and 14 should be changed to the phrases "a device for performing" and "a device for removing".

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 59-82 and 84-107 are rejected under 35 U.S.C. 102(b) as being anticipated by Iketaki et al (WO 99/60391, English language translation is US patent no. 6,576,117).

Iketaki et al teach of a method for electrochemically measuring the concentration of a first medically significant analyte in a sample in the presence of a second analyte, which affects the determination of the first analyte. Iketaki et al teach that the first analyte is glucose in a blood sample whose concentration is affected by the hematocrit value of the blood sample that causes errors in the measurement result of glucose. See lines 13-21 in column 2 of Iketaki et al. Iketaki et al teach that a biosensor is used to perform the method by applying a predetermined voltage to the biosensor twice to promote an electrochemical reaction. Two measurements of current are made and a statistical technique is used with the measurements to compensate for the errors in the glucose concentration made by the hematocrit. In a first measurement, a voltage is applied to a glucose sensor at a time=0 for a period of seven seconds for a first excitation. The current is measured at every 0.1 seconds so that the first measurement has the form of a time-varying function I(t). The difference in the current profile during the first excitation varies with only the concentration and presence of the physical properties of the blood sample such as hematocrit. In a second measurement, a subsequent five-second application of voltage is applied to the glucose sensor in order to detect a difference in the current profile caused by the combined affects of the concentration of glucose in the blood sample and the hematocrit of the sample.

The measured current in the second measurement is then corrected for the affects of hematocrit by a series of statistical calculations. See lines 21-67 in column 10 and lines 1-50 in column 11 of Iketaki et al. The corrected current value I'(5) is then converted into a glucose concentration value by using a calibration curve table.

6. Claims 109 and 133 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, first and second paragraphs, set forth in this Office action since none of the prior art of record teaches or fairly suggests a method for determining the concentration of a first medically significant component (i.e. glucose) in a biological sample (i.e. blood) in the presence of a second component (i.e. hematocrit) that affects the determination of the first component by performing a first measurement of a time-varying function i1(t) of a biological fluid, wherein i1(t) varies with both the concentration of the first component and the presence or concentration of the second component and has the formula as outlined in claims 109 and 133, performing a second measurement on the biological fluid which varies with only the presence or concentration of the second component, and removing the amount representative of the second component from the concentration of the first component indicated by the first measurement.

7. Claims 83, 108, 110, 115-116, 121-122, 127-128 and 134-156 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, first and second paragraphs, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims for the same reasons as given above.

8. Claims 111-114, 117-120, 123-126 and 129-132 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims for the same reasons as given above.

9. Applicant's arguments filed December 21, 2004 have been fully considered but they are not persuasive.

Applicant argues the rejection of the claims under 35 USC 112, first paragraph as being non-enabling for the determination of the concentration of any other component than glucose in any other biological fluid than blood in the presence of any other interferant than hematocrit by stating that the Examiner is attempting to limit all of the claims to the specific example given in the specification when the specification cites several prior art publications incorporated by reference that cite other analytes besides glucose. In response to this argument, it is noted that there is no evidence given that the analytes taught in the cited prior art publications can be analyzed and detected by the method and apparatus recited in the instant claims. The only evidence supplied by the instant specification is that these other analytes can be measured and detected with the prior art methods set out in the cited publications incorporated by reference. No evidence is shown in the instant specification that these other analytes can be measured and detected using the steps and device of the instant invention.

In support of the instant specification being enabling for the broadly recited claims, Applicant also argues that the instant specification states that "the invention is useful in other systems besides glucose concentration and hematocrit", and that "other analytes can be detected and their concentration in a sample determined and reported". In response to this argument, it is noted that these statements in the instant specification are merely prophetic statements or

examples that do not support a reduction of the instant invention to practice for the analysis of analytes other than glucose in the presence of interferants other than hematocrit. The only concrete example given in the instant specification in support of the broadly recited claims is the determination of glucose in blood in the presence of hematocrit. More than one concrete example with factual evidence is needed to support the broad scope of the claims as presently recited. Predictions and prophetic examples do not enable the instant claims for the analysis of any analyte in any biological fluid and in the presence of any interfering compound.

Applicant argues the rejection of the claims under 35 USC 102(b) as being anticipated by Iketaki by stating that Iketaki uses a statistical approach to correct an indicated analyte concentration for the concentration of an interferant, whereas the instant invention uses an actual measurement of the concentration of an interferant to correct for the measurement of the indicated analyte concentration. In response to this argument, it is noted that the statistical calculations taught by Iketaki are used to obtain or calculate the concentrations of glucose and the interferant, i.e. hematocrit (HCT). See lines 19-21 in column 11 of Iketaki where the concentration of glucose is determined from the value of I'(5) and a calibration curve table. In addition, see lines 65-67 in column 10 and lines 1-12 in column 11 of Iketaki where a value "z" is calculated that reflects the amount or concentration of hematocrit in a blood sample. Therefore, the method taught by Iketaki also uses a measurement of the actual concentration of an analyte and its interferant to obtain a correction of an indicated analyte concentration for the concentration of an interferant in the same manner as the instant invention. The statistical calculations taught by Iketaki are merely used for converting the current measurements in the biosensor to numerical concentrations.

For all of the above reasons, Applicant's arguments are not found persuasive.

10. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

March 8, 2005

Maureen M. Wallenhorst
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